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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q90374

Young Min KIM, et al.

Appln. No.: 10/551,764

Group Art Unit: Unassigned

Confirmation No.: Unknown

Examiner: Unassigned

Filed: October 3, 2005

For: PEG-PHYSIOLOGICALLY ACTIVE POLYPEPTIDE HOMODIMER COMPLEX
HAVING PROLONGED IN VIVO HALF-LIFE AND PROCESS FOR THE
PREPARATION THEREOF

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

1. Brian C. Cunningham et al., "Rational design of receptor-specific variants of human growth hormone", *Proc. Natl. Acad. Sci. USA*, Vol. 88, April 1991, pp. 3407-3411.
2. Dieter Haffner et al., "Metabolic Clearance of Recombinant Human Growth Hormone in Health and Chronic Renal Failure", *J. Clin. Invest.*, Vol. 93, March 1994, pp. 1163-1171.
3. Ross Clark et al., "Long-acting Growth Hormones Produced by Conjugation with Polyethylene Glycol", *The Journal of Biological Chemistry*, Vol. 271, No. 36, Sept. 6, 1996, pp. 21969-21977.

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U.S. Appln. No.: 10/551,764
INFORMATION DISCLOSURE STATEMENT

4. Yoshinobu Fukumori et al., "Coating of Pharmaceutical Powders by Fluidized Bed Process. III. Aqueous Coating with Ethyl Acrylate-Methyl Methacrylate-2-Hydroxyethyl Methacrylate Copolymer and the Dissolution Properties of the Products", *Chem. Pharm. Bull.*, Vol. 36, 1988, pp. 3070-3078.
5. Steven M. Chamow et al., "Modification of CD4 Immunoadesin with Monomethoxypoly(ethylene glycol) Aldehyde via Reductive Alkylation", *Bioconjugate Chem.*, Vol. 5, 1994, pp. 133-140.
6. Liew-Cheng Teh & George E. Chapman, "Determination of the Effect of Acetylation of Specific Lysine Residues in Human Growth Hormone on its Affinity for Somatogenic Receptors by an Affinity Selection Technique", *Biochemical and Biophysical Research Communications*, Vol. 150, No. 1, January 15, 1988, pp. 391-398.
7. A. L. Baldwin et al., "Bioactivity and immunoactivity of growth hormone during dynamic testing of patients with acromegaly", *Acta Endocrinologica (Copenh)*, Vol. 119, 1988, pp. 326-332.
8. M. Bozzola et al., "Evaluation of growth hormone bioactivity using the Nb₂ cell bioassay in children with growth disorders", *J. Endocrinol. Invest.*, Vol. 21, 1998, pp. 765-770.
9. James A. Wells et al., "The Molecular Basis for Growth Hormone-Receptor Interactions", *Recent Progress in Hormone Research*, Vol. 48, 1993, pp. 253-275.

One copy of each of the listed documents is submitted herewith.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

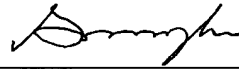
The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not

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waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,



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of

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Application Number	10/551,764
Confirmation Number	Unknown
Filing Date	October 03, 2005
First Named Inventor	Young Min KIM
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	Q90374

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code ² (if known)		
		US			
		US			
		US			
		US			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)			

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶
		Brian C. Cunningham et al., "Rational design of receptor-specific variants of human growth hormone", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 88, April 1991, pp. 3407-3411	
		Dieter Haffner et al., "Metabolic Clearance of Recombinant Human Growth Hormone in Health and Chronic Renal Failure", <i>J. Clin. Invest.</i> , Vol. 93, March 1994, pp. 1163-1171	
		Ross Clark et al., "Long-acting Growth Hormones Produced by Conjugation with Polyethylene Glycol", <i>The Journal of Biological Chemistry</i> , Vol. 271, No. 36, Sept. 6, 1996, pp. 21969-21977	
		Yoshinobu Fukumori et al., "Coating of Pharmaceutical Powders by Fluidized Bed Process. III. Aqueous Coating with Ethyl Acrylate-Methyl Methacrylate-2-Hydroxy-ethyl Methacrylate Copolymer and the Dissolution Properties of the Products", <i>Chem. Pharm. Bull.</i> , Vol. 36, 1988, pp. 3070-3078	
		Steven M. Chamow et al., "Modification of CD4 Immunoconjugate with Monometh-oxypoly(ethylene glycol) Aldehyde via Reductive Alkylation", <i>Bioconjugate Chem.</i> , Vol. 5, 1994, pp. 133-140	
		Liew-Cheng The & George E. Chapman, "Determination of the Effect of Acetylation of Specific Lysine Residues in Human Growth Hormone on its Affinity for Somatogenic Receptors by an Affinity Selection Technique", <i>Biochemical and Biophysical Research Communications</i> , Vol. 150, No. 1, January 15, 1988, pp. 391-398	
		A. L. Baldwin et al., "Bioactivity and immunoactivity of growth hormone during dynamic testing of patients with acromegaly", <i>Acta Endocrinologica (Copenh)</i> , Vol. 119, 1988, pp. 326-332	
		M. Bozzola et al., "Evaluation of growth hormone bioactivity using the Nb ₂ cell bioassay in children with growth disorders", <i>J. Endocrinol. Invest.</i> , Vol. 21, 1998, pp. 765-770	
		James A. Wells et al., "The Molecular Basis for Growth Hormone-Receptor Interactions", <i>Recent Progress in Hormone Research</i> , Vol. 48, 1993, pp. 253-275	

Examiner Signature

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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